

III. REMARKS

Claims 1-19 and 26-34 were previously pending. No claims have been added or canceled. Reconsideration of presently pending claims 1-19 and 26-34 is respectfully requested in light of the above amendments and the following remarks.

Double Patenting

Claims 1-19 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 101-103, 106-110, 112-113 of copending U.S. Patent Application Ser. No. 09/924,298. Applicants again acknowledge this provisional rejection and will address any double patenting issues if and when a double patenting problem comes to fruition.

§102 Rejections

Claims 1, 2, 17-19, 26-29, 32, and 33 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,290,726 to Pope et al. ("the Pope patent"). Applicants traverse this rejection for at least the following reasons.

The PTO provides in MPEP § 2131 that

"[t]o anticipate a claim, the reference must teach every element of the claim...."

Therefore, to sustain the rejection of these claims the Pope patent must teach all of the claimed elements. However, the Pope patent fails to disclose all of the claimed elements of independent claims 1, 2, and 26 and, therefore, dependent claims 17-19, 27-29, 32, and 33.

With respect to independent claim 1, the Pope patent at least fails to teach "a first component having an articular surface for articulated movement with the shell, the first component formed from a wear resistant first material, and a second component formed from a resilient second material." The Office Action appears to assert that the substrate 2053c of the disk core 2053 is formed of a resilient material. However, the Pope patent describes in detail the

materials that may be utilized as substrates in forming the polycrystalline diamond compact.

None of the metals described as possible substrates appear to be resilient materials as required by claim 1. For example, the Pope patent states:

“The substrate 410 may be a suitable pure metal or alloy, or a cemented carbide containing a suitable metal or alloy as a cementing agent such as cobalt-cemented tungsten carbide. Preferably the substrate will be a metal with high tensile strength.”
Col. 22, Lines 53-57

“The unique material properties of diamond and its relative differences in modulus and CTE compared to most potential substrate materials diamond make selection of an appropriate polycrystalline diamond substrate a formidable task. When the additional constraints of biocompatibility is placed on the substrate, the choice is even more difficult. Most biocompatible metals are not compatible with the material properties of synthetic diamond.” Col. 34, Lines 2-9

“In order to manufacture any polycrystalline diamond component, an appropriate substrate should be selected. For the manufacture of a polycrystalline diamond component to be used in a prosthetic joint, the inventors prefer use of the substrates listed in the table below.

TABLE 2

<u>SOME SUBSTRATES FOR BIOMEDICAL APPLICATIONS</u>		
SUBSTRATE	ALLOY NAME	REMARKS
Titanium	Ti6Al4V (TiAlV ₄) ASTM F-1313 (TiNbZr) ASTM F-620 ASTM F-1580 TiMnHf Nitinol (TiNi + other)	A thin tantalum barrier is preferably placed on the titanium substrate before loading diamond feedstock. Approved biocompatible material.
Cobalt chrome	ASTM F-799	Contains cobalt, chromium and molybdenum. Wrought product. Approved biocompatible material.
Cobalt chrome	ASTM F-90	Contains cobalt, chromium, tungsten and nickel. Approved biocompatible material.
Cobalt chrome	ASTM F-75	Contains cobalt, chromium and molybdenum. Cast product. Approved biocompatible material.
Cobalt chrome	ASTM F-562	Contains cobalt, chromium, molybdenum and nickel. Approved biocompatible material.
Cobalt chrome	ASTM F-563	Contains cobalt, chromium, molybdenum, tungsten, iron and nickel. Approved biocompatible material.
Tantalum	ASTM F-560 (unalloyed)	Approved biocompatible refractory metal.
Platinum	various	
Niobium	ASTM F-67 (unalloyed)	Approved biocompatible refractory metal.
Manganese	Various	May include Cr, Ni, Mg, molybdenum.
Cobalt cemented tungsten carbide	WC	Not approved in the U.S. for prosthetic applications at the time of writing.
Cobalt chrome cemented tungsten carbide	CoCr cemented WC	CoCr is an approved biocompatible material.
Cobalt chrome cemented chrome carbide	CoCr cemented CrC	CoCr is an approved biocompatible material.
Cobalt chrome cemented silicon carbide	CoCr cemented SiC	CoCr is an approved biocompatible material.
Fused silicon carbide	SiC	
Cobalt chrome molybdenum	CoCrMo	A thin tungsten or tungsten/cobalt layer is placed on the substrate before loading diamond feedstock.
Stainless steel	Various	Approved biocompatible material.

Cols. 35-36, Lines 1-50.

Therefore, for at least this reason the Pope patent fails to teach every element of independent claim 1. Claim 17 depends from and further limits claim 1. Thus, Applicants respectfully request that the §102 rejection of claims 1 and 17 over the Pope patent be withdrawn.

Further, as the Pope patent specifically points out that finding a suitable substrate for the polycrystalline diamond component surfaces is “a formidable task” and becomes “even more difficult” once biocompatibility constraints are taken into account, it is clear that the polycrystalline diamond surfaces cannot simply be combined with a resilient substrate material. Also, it should be noted that the inventors’ preferred substrates listed in Table 2 of the Pope patent are all metals and metal alloys. Therefore, in addition to failing to teach all of the claimed elements of claim 1, the Pope patent cannot be used to establish a prima facie case of obviousness under 35 U.S.C. §103 with respect to claims 1 and 17.

Similarly, independent claim 2 recites in part, “a first component having an articular surface for articulated movement with the shell, the first component formed from a wear resistant first material, and a second component formed from a resilient second material, wherein the second component is disposed between the first component and a third component also formed from the first material, the third component having an articular surface for articulated movement with the shell.” As shown above, the Pope patent fails to disclose a second component formed from a resilient material. Therefore, for at least the same reasons the Pope patent fails to anticipate or render obvious independent claim 2. Claims 18 and 19 depend from and further limit claim 2. Thus, Applicants respectfully request that the §102 rejection of claims 2, 18, and 19 over the Pope patent be withdrawn.

With respect to independent claim 26, the Pope patent at least fails to teach, “a first portion configured to articulate with a first surface of the shell structure, the first portion formed from a first wear-resistant material; a second portion configured to articulate with a second surface of the shell structure, the second portion formed from a second wear-resistant material; and a third portion positioned at least partially between the first and second portions to avoid contact with the shell structure, the third portion formed from a resilient material.” As shown above, the Pope patent fails to disclose a third portion formed of a resilient material as required.

Therefore, for at least the same reasons the Pope patent fails to anticipate or render obvious independent claim 26. Claims 27-29, 32, and 33 depend from and further limit claim 26. Thus, Applicants respectfully request that the §102 rejection of claims 26-29, 32, and 33 over the Pope patent be withdrawn.

§103 Rejections

Claims 3-7 and 10-16 stand rejected under 35 U.S.C. §103 as being unpatentable over the Pope patent.

The PTO provides in MPEP §2131 that:

“The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.”

The Examiner clearly cannot, using the Pope patent, establish a prima facie case of obviousness with respect to these claims for at least the following reasons.

35 U.S.C. §103(a) provides, in part, that:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . .” (emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, as shown above the Pope patent fails to teach all of the elements of independent claim 1, from which claims 3-7 and 10-16 depend and further limit. Thus, a prima facie case of obviousness has not been established with respect to claims 3-7 and 10-16. Therefore, Applicants respectfully request that the §103 rejection of claims 3-7 and 10-16 over the Pope patent be withdrawn.

Claims 30 and 31 stand rejected under 35 U.S.C. §103 as being unpatentable over the Pope patent in view of U.S. Patent No. 5,401,269 to Buttner-Janz et al. (“the Buttner-Janz patent”). However, as shown above the Pope patent fails to teach all of the elements of

independent claim 26, from which claims 30 and 31 depend and further limit. The Buttner-Janz patent does not affect this deficiency. Thus, a prima facie case of obviousness has not been established with respect to claims 30 and 31. Therefore, Applicants respectfully request that the §103 rejection of claims 30 and 31 over the Pope and Buttner-Janz patents be withdrawn.

Claim 34 stands rejected under 35 U.S.C. §103 as being unpatentable over the Pope patent in view of U.S. Patent No. 6,395,034 to Suddaby (“the Suddaby patent”). With respect to independent claim 34, the Office Action notes that the Pope patent “teach[es] all the limitations, except for a recess in the first portion and a projection in the second portion; as claimed by applicant.” However, as shown above the Pope patent at least fails to disclose a third portion formed from a resilient material as required. Accordingly, even when combined the Pope and Suddaby patents fail to disclose all of the recited elements of claim 34. Thus, for at least these reasons a prima facie case of obviousness has not been established with respect to claim 34. Therefore, Applicants respectfully request that the §103 rejection of claim 34 over the Pope and Suddaby patents be withdrawn.

IV. Conclusion

It is believed that all matters set forth in the Final Office Action have been addressed, and that claims 1-19 and 26-34 are in condition for allowance. An early indication of allowance of the claims is respectfully requested.

Should the Examiner deem that an interview with Applicant's undersigned attorney would expedite consideration, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

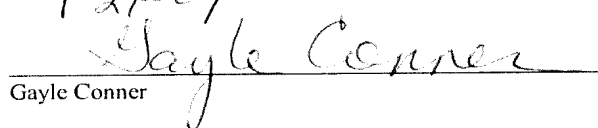


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